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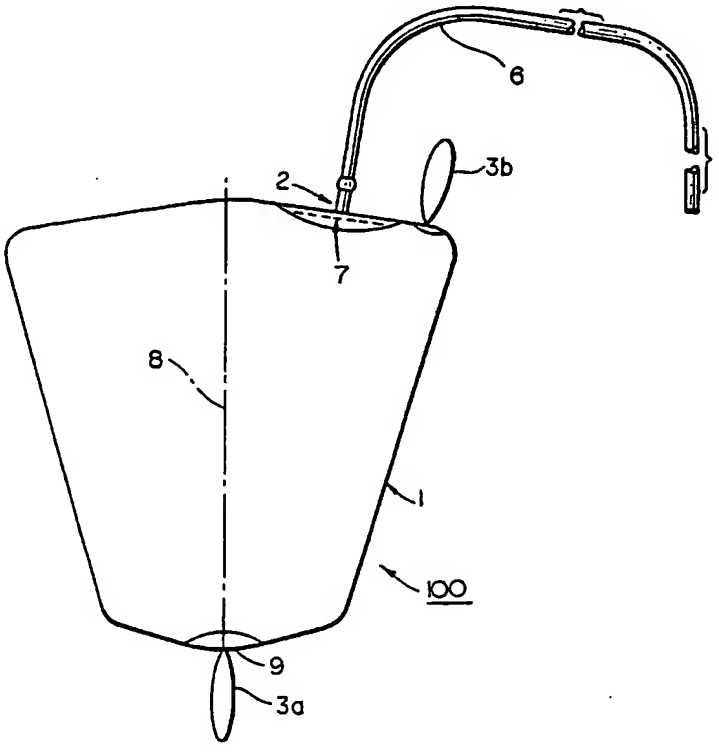
(54) Title: PELVIC DISPLACEMENT PROSTHESIS FOR RADIOPROTECTION OF THE SMALL BOWEL



(57) Abstract: A pelvic displacement prosthesis (100) for the radioprotection of the small bowel is provided. The prosthesis includes a shell (1) having a hollow frustum shape with one or more manipulation loops (3a, 3b) affixed thereto. A method for displacing the small bowel is also provided.

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PELVIC DISPLACEMENT PROSTHESIS FOR RADIOPROTECTION OF THE SMALL BOWEL

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a pelvic displacement prosthesis for radioprotection of the small intestines (bowel), and a method therefor, in which the prosthesis is inserted into the pelvis to elevate the small bowel out of the pelvic cavity during radiation therapy.

2. Description of the Related Art

Radiation can be an effective therapy in early stage cervical carcinoma and is the treatment of choice in later stage disease. Typically, the patient receives between 4500 and 5040 centiGray (rads) of radiation via external beam teletherapy to the whole pelvis followed with brachytherapy implants which are placed directly on the tumor. The purpose of the whole pelvic radiation is to sterilize microscopic disease which may be in the lymph nodes, as well as to shrink the size of the primary tumor. The dosage to the whole pelvis is calculated to be within small bowel tolerance to radiation. The other primary structures in the pelvis, the bladder and colon, have a greater tolerance to radiation. If the radiation dosage to the pelvis could be raised without increasing the rate of radiation-related bowel complications, then the curative potential of the radiation would be enhanced.

Several methods have been described to keep the small bowel out of the pelvis during radiation. Historically, various slings made out of omentum or synthetic meshes have been attempted to keep the small bowel above the pelvic brim. Several devices have been tried which physically occupy the pelvic cavity such as breast implants, and "belly boards" to maintain the small bowel out of the pelvic cavity.

More recently, a prosthetic bladder has been utilized which is connected via tubing to a subcutaneous port so that the device can be insufflated or desufflated as needed during radiation therapy to elevate the small intestines out of the pelvic cavity. The device was used on 11 patients with none developing a complication in the follow-up period. The usual

tolerable dose of radiation to the pelvis was increased in several patients secondary to the protection of the small intestine. This device was placed through a laparotomy and required a second small laparotomy to remove the instrument. In addition, an infusion port was placed beneath the skin of the abdomen to access the prosthetic bladder. This requires a separate incision to remove. While the inflated device did produce discomfort related to bowel and bladder pressure in some patients, inflation need occur only during the time the patient is receiving radiation, then the prosthetic bladder can be deflated for the remainder of the day.

Studies of these prior art devices revealed complications with small bowel tears due to adhesions and shearing forces at the time such devices were removed.

The shape, conformity, and soft texture of the pelvic displacement prosthesis of present invention is ideal for placing into the pelvis and leaving in place for the duration of radiation. Constant, rather than intermittent, insufflation of the device causes less discomfort to the patient.

The prosthesis of the present invention integrates an expandable shell of sufficient shape and volume to elevate the small intestine out of the pelvic area during radiation when insufflated or filled. The prosthesis is connected via tubing to a valve or infusion port and can be filled with saline or other biologically compatible fluids. The tubing is located on the anterior or distal end of the device, so that, when the prosthesis is in place, the tubing will be located next to the anterior abdominal wall and away from the small intestine.

The prosthesis of the present invention is designed so that, in its unfilled state, the prosthesis is of a size and shape that it can be placed and removed without a major surgical procedure. Because of the location of the tubing, the device may be removed by pulling on the tubing to bring the prosthesis up through the fascia such that any shearing forces are away from the small intestine thereby minimizing the risk of tearing the bowel.

SUMMARY OF THE INVENTION

In order to solve the problems associated with the prior-art devices and methods described above, the invention provides for a novel pelvic displacement prosthesis for radioprotection of the small bowel.

In a first embodiment, the pelvic displacement prosthesis includes a hollow frustum-shaped shell.

In another embodiment, the pelvic displacement prosthesis includes a hollow shell and one or more manipulation loops affixed to the exterior thereof.

In a further embodiment, the pelvic displacement prosthesis includes a hollow frustum-shaped shell and one or more manipulation loops affixed to the exterior thereof .

The pelvic displacement prosthesis is inserted into the pelvis of a patient via an incision, laparotomy or laparoscopy. One or more manipulation loops are used to position the prosthesis within the pelvis. Fluid is supplied to or removed from the prosthesis through a tube connected to a valve or infusion port to insufflate or desufflate the shell.

During treatment, radiation is applied to the desired area of the pelvis. Following treatment, the empty prosthesis is removed through an incision, laparotomy or laparoscopy using the tube or one or more of the manipulation loops.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is an elevation view of a pelvic displacement prosthesis embodying aspects of the invention.

Fig. 2 is a plan view of a pelvic displacement prosthesis embodying aspects of the invention.

DETAILED DESCRIPTION OF THE DRAWINGS

This embodiment of the pelvic displacement prosthesis is expandable with a capacity on the order of 750 - 1500 cc without approaching its restrictive compliance (*i.e.* without

approaching a shell's bursting point). The shape of the prosthesis is such that upon insufflation it will conform to the pelvic anatomy, such as a circular or other shaped frustum. The prosthesis may be made with one or more manipulation loops which can be sewn to the peritoneum at approximately the pelvic brim and at the base of the exenteration (tumor) site. Some advantages of this feature of the prosthesis are the ease of insertion and removal of the prosthesis, and the ability to secure the prosthesis within the pelvis to prevent slippage of small intestine around the prosthesis which could become fixed in the radiation field. This embodiment of the prosthesis is made of material safe for long-term (2-3 months) intraperitoneal placement, such as silicone elastomer. This embodiment of the prosthesis is minimally radio-opaque so that the pelvis can be evaluated by standard radiologic procedures if a problem were to develop while on therapy. This embodiment of the prosthesis is fluidly connected to an infusion port via silicone tubing approximately 24 inches long so that it can be safely routed to an exit site out of the radiation field.

Fig. 1 is an elevation view, and Fig. 2 is a plan view, of a pelvic displacement prosthesis **100** embodying aspects of the present invention. The pelvic displacement prosthesis **100** includes shell **1**, valve patch **2**, manipulation loops **3a**, **3b** and tubing **6**.

Shell **1** has a hollow frustum, or truncated-cone, shape having an axis **8**. The radius of the proximal end of shell is smaller than that of its distal end. The proximal and distal ends of shell **1** have outwardly-projecting shallow conical surfaces. The extreme distal end of shell **1** is reinforced by reinforcement sheet **5**.

Valve patch **2** is affixed via a fluid-tight connection to the distal end of shell **1**. The axis of valve patch **2** is located at a radial distance **A** from the outer diameter of the distal end of shell **1**. The connection between shell **1** and valve patch **2** is reinforced by reinforcement sheet **7**. Tubing **6** is affixed via a fluid-tight connection to valve patch **2**.

Manipulation loop **3a** is permanently affixed to the extreme proximal end of shell **1** along axis **8**. Manipulation loop **3b** is permanently affixed to the distal end of shell **1** at a radial distance **B** from the outer diameter of the distal end of shell **1**. The attachments of manipulation loops **3a** and **3b** are reinforced by reinforcement sheets **9** and **10**, respectively.

In a preferred embodiment, the height of shell **1** is approximately 139 mm, the diameters of the proximal and distal ends of shell **1** are approximately 83 mm and 153 mm, respectively, and radial distances **A** and **B** are 30 mm and 20 mm, respectively.

The pelvic displacement prosthesis of the present invention is useful for patients undergoing surgical staging for advanced carcinoma of the cervix and other surgeries requiring radioprotection of the small bowel. Typically, patients first have a laparotomy performed with para-aortic lymph nodes removed via a retroperitoneal approach. Any large or suspicious lymph nodes in the pelvis will also be removed if at all feasible. At the completion of surgery, the pelvic displacement prosthesis is placed, using manipulation loops **3a** and **3b**, into the pelvis and stitched, using absorbable sutures, onto the peritoneum and pelvis. The prosthesis is then insufflated with normal saline to a sufficient volume to displace the small intestine above the pelvic brim. The amount of fluid required is noted for each patient. The tubing of the prosthesis is brought up through the abdominal wall and attached to the fascia in a location outside the radiation field and connected to an infusion port. The prosthesis is tested prior to closure of the abdomen for ease of filling through the infusion port.

Patients then undergo radiation therapy after recovery from their laparotomy in the usual manner. The patients may have a small bowel radiographic series performed prior to radiation to document displacement of the small bowel by the pelvic displacement prosthesis.

In another method, the pelvic displacement prosthesis may be insufflated with saline containing a small amount of radioopaque dye to aid in documenting displacement of the small bowel by the pelvic displacement prosthesis.

At the completion of therapy, a small incision over the infusion port is performed using local anesthesia and intravenous sedation. The infusion port is detached from the fascia and a small incision is made in the fascia just below this through which the pelvic displacement prosthesis is removed from the patient after desufflation of all the saline. The wound in the fascia and skin is closed in a customary fashion.

In another method, the pelvic displacement prosthesis may be placed within the pelvis or removed therefrom laparoscopically, *i.e.* via a cannula or trocar.

This pelvic displacement prosthesis and method have at least the following benefits:

1. Decreased damage to the small bowel.

The most frequent cause of operation due to morbidity from radiation for cancer of the cervix involves small bowel injury. The small intestines are constantly moving with peristaltic activity and, therefore, should receive less radiation than the stationary structures of the pelvis. However, after surgeries for carcinoma of the cervix there is a higher likelihood of adhesion formation which tethers the small intestine and allows more radiation to be delivered to a finite portion, increasing the risk of reaching tissue tolerance. Volumes of the pelvis can range from 600-1000 cc. A device which can be expanded to 1500 cc will adequately elevate the small intestine out of the radiation field.

2. Increased radiation to the pelvis.

As previously mentioned, the typical dose to the whole pelvis is sufficient to sterilize (*i.e.* kill) microscopic metastases of tumor to the pelvic lymph nodes. After radiation therapy, a significant number of patients are at risk for lymph node metastases that will recur in the pelvis, often in the area of the pelvic lymph nodes. With the removal of the small

intestines from the pelvis, the whole pelvic dose can be raised to the level of tolerance for the sigmoid colon – about 6000 rads – which should sterilize larger tumor volumes. This can have a significant impact on patient survival for those patients with unresectable or unresected lymph nodes, or those at high risk for having lymph node metastases.

3. Ease to patients.

This device can be implanted at the time of laparotomy for staging of cervical cancer. The infusion port is brought out through the skin and secured with a suture to the anterior abdominal wall. This position assures that with insufflation of saline into the pelvic displacement prosthesis, the small intestines are elevated outside the pelvic cavity. The infusion port is then be tunneled under the skin to a separate exit site to decrease the likelihood of infection along the tubing.

4. Economics.

At the completion of therapy, the device can be removed in the office with local anesthesia, causing minimal inconvenience to patients.

It is to be understood that the above-described embodiments are merely illustrative of the principles of the invention and that other arrangements may be devised by those skilled in the art without departing from the spirit and scope of the invention.

What is claimed is:

1. A pelvic displacement prosthesis for radioprotection of the small bowel comprising a shell having a hollow frustum shape.

2. The pelvic displacement prosthesis of claim 1 further comprising a tube affixed to and in fluid communication with the interior of said shell.

3. The pelvic displacement prosthesis of claim 2 wherein said shell includes a proximal end and a distal end, wherein said distal end is larger than said proximal end, and said tube is affixed to said distal end.

4. The pelvic displacement prosthesis of claim 3 wherein said distal end has an outer edge, and said tube is affixed at a distance inward of said outer edge.

5. The pelvic displacement prosthesis of claim 1 wherein said shell includes proximal and distal ends, at least one of said ends having a outwardly projecting surface.

6. The pelvic displacement prosthesis of claim 1 wherein said shell has a substantially circular hollow frustum shape.

7. A pelvic displacement prosthesis for radioprotection of the small bowel comprising a hollow shell having proximal and distal ends, said shell having one or more manipulation loops affixed thereto.

8. The pelvic displacement prosthesis of claim 7 wherein a proximal manipulation loop is affixed to said proximal end.

9. The pelvic displacement prosthesis of claim 8 wherein said proximal end has a center of area, and said proximal manipulation loop is affixed approximately at said center of area.

10. The pelvic displacement prosthesis of claim 7 wherein a distal manipulation loop is affixed to said distal end.

11. The pelvic displacement prosthesis of claim 10 wherein said distal end has an outer edge, and said distal manipulation loop is affixed at a distance inward from said outer edge.

12. The pelvic displacement prosthesis of claim 7 further comprising a tube affixed to and in fluid communication with the interior of said shell.

13. The pelvic displacement prosthesis of claim 12 wherein said distal end has an outer edge, and said tube is affixed at a distance inward of said outer edge.

14. A pelvic displacement prosthesis for radioprotection of the small bowel comprising a shell having a hollow frustum shape and proximal and distal ends, said shell having one or more manipulation loops affixed thereto.

15. The pelvic displacement prosthesis of claim 14 further comprising a tube affixed to and in fluid communication with the interior of said shell.

16. The pelvic displacement prosthesis of claim 15 wherein said distal end is larger than said proximal end, and said tube is affixed to said distal end.

17. The pelvic displacement prosthesis of claim 16 wherein said distal end has an outer edge, and said tube is affixed at a distance inward from said outer edge.

18. The pelvic displacement prosthesis of claim 14 wherein at least one of said ends has a outwardly projecting surface.

19. The pelvic displacement prosthesis of claim 14 wherein said shell has a substantially circular hollow frustum shape.

20. The pelvic displacement prosthesis of claim 14 wherein a proximal manipulation loop is affixed to said proximal end.

21. The pelvic displacement prosthesis of claim 20 wherein said proximal end has a center of area, and said proximal manipulation loop is affixed approximately at said center of area.

22. The pelvic displacement prosthesis of claim 14 wherein a distal manipulation loop is affixed to said distal end.

23. The pelvic displacement prosthesis of claim 22 wherein said distal end has an outer edge, and said distal manipulation loop is affixed at a distance inward from said outer edge.

24. A radioprotection prosthesis for displacing the small bowel from the pelvis comprising:

means for displacing the small bowel from the pelvis whereby said displacing means substantially conforms to an interior shape of the pelvis, and

means for manipulating said displacing means and affixed thereto.

25. The radioprotection prosthesis of claim 24 further comprising means for the transmission of fluid, said fluid transmission means in fluid communication with said displacing means.

26. A method of displacing the small bowel from the pelvis comprising:

introducing a hollow-shelled prosthesis into the pelvis,

manipulating said prosthesis within the pelvis using one or more loops affixed to said prosthesis, and

insufflating said prosthesis with a fluid.

27. The method of claim 26 wherein said insufflation includes substantially conforming said prosthesis to the shape of said pelvis.

28. The method of claim 26 wherein said fluid contains a radioopaque dye.

29. The method of claim 26 wherein at least one of said loops is affixed to the proximal end of said prosthesis.

30. The method of claim 26 further comprising securing said prosthesis within the pelvis.

31. The method of claim 26 where said prosthesis is laparoscopically introduced into the pelvis.

32. A method of displacing the small bowel from the pelvis comprising:

introducing a hollow-shelled prosthesis having a frustum shape into the pelvis, and

insufflating said prosthesis with a fluid.

33. The method of claim 32 wherein said insufflation includes substantially conforming said prosthesis to the shape of said pelvis.

34. The method of claim 32 wherein said fluid contains a radioopaque dye.

35. The method of claim 32 wherein said prosthesis has a substantially circular hollow frustum shape.

36. The method of claim 32 further comprising securing said prosthesis within the pelvis.

37. The method of claim 32 where said prosthesis is laparoscopically introduced into the pelvis.

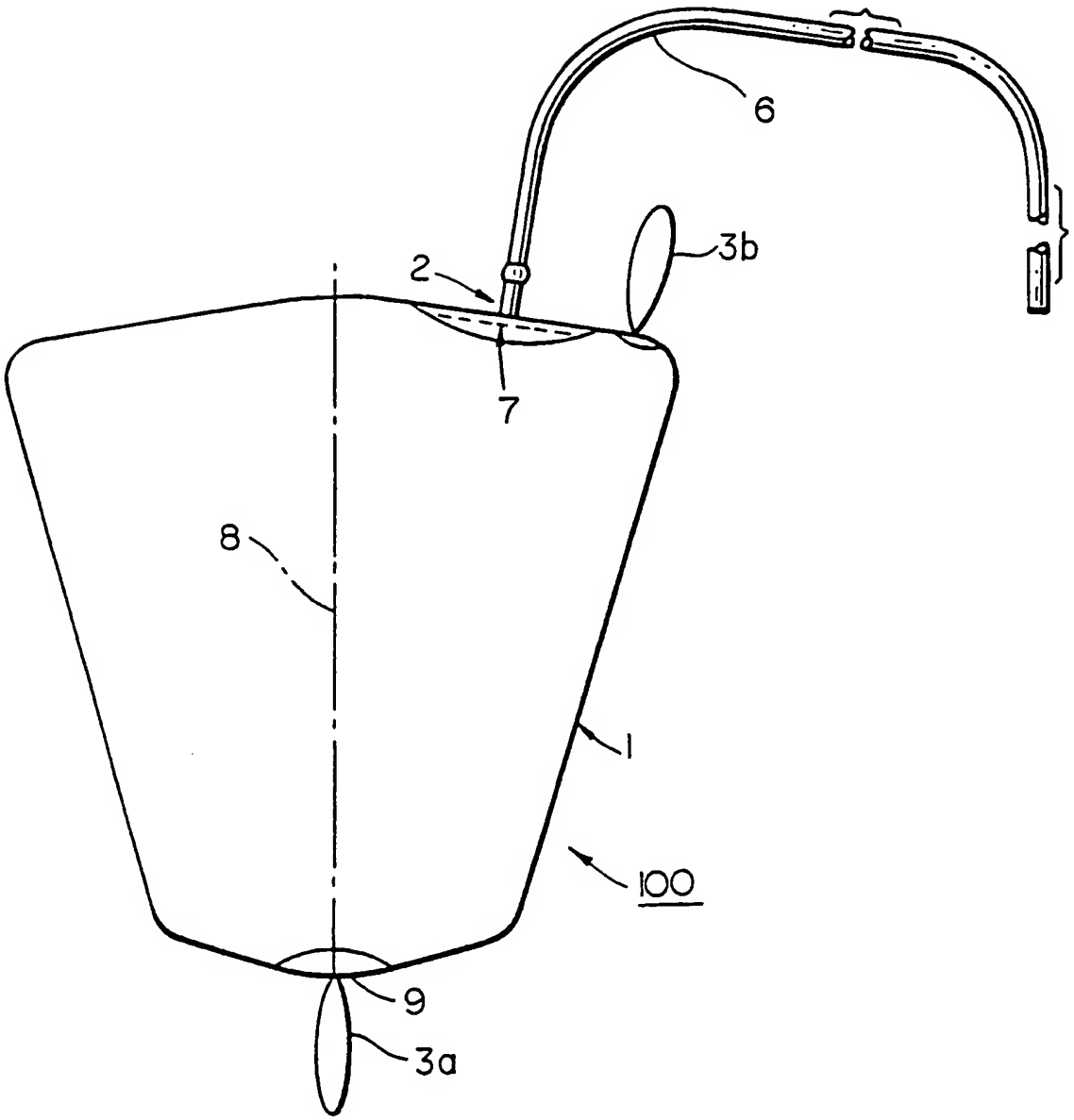

FIG. 1

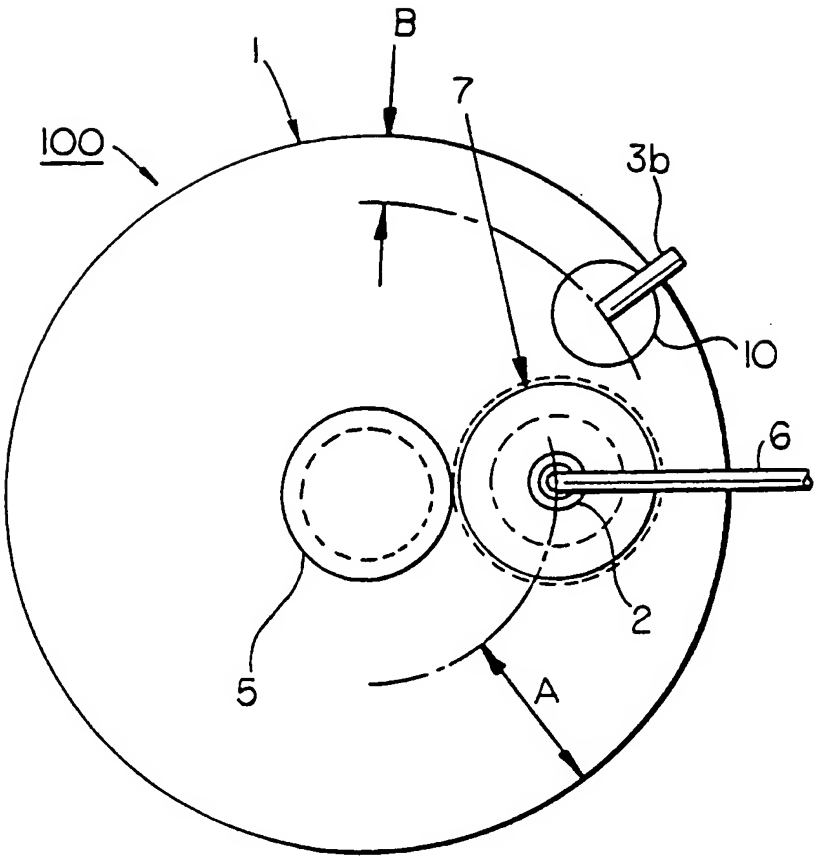

FIG. 2

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/12220

A. CLASSIFICATION OF SUBJECT MATTER
IPC(6) :A61B 10/00; A61F 2/12
US CL :128/898; 600/37; 623/11
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED
Minimum documentation searched (classification system followed by classification symbols)
U.S. : 128/898; 600/37; 623/11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 5,735,791 A (ALEXANDER, JR. et al.) 07 April 1998, Fig. 4, and cols. 1-6.	1-6, 24, 25
Y	US 5,337,754 A (HEAVEN et al.) 16 August 1994, Fig. 5b, and cols. 1-4.	1-6, 24, 25
Y	US 4,950,292 A (AUDRETSCH) 21 August 1990, Figs. 1-5, and cols. 1-17.	1-6, 24, 25
Y	US 4,944,749 A (BECKER) 31 July 1990, Figs. 1-6, and cols. 1-7.	1-6, 24, 25
Y	US 4,643,733 A (BECKER) 17 February 1987, Figs. 1-3, and cols. 1-7.	1-6, 24, 25

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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